United States Court of Federal Claims

No. 05-1002 V

(Filed Under Seal: November 25, 2008)

(**Reissued**: December 10, 2008)[*]

MELISSA CLOER, M.D.,

***Petitioner*,**

Vaccine Act; Vaccine Injury; Statute of Limitations; *Markovich;* Symptom versus Manifestation; Diagnosis; Constitutional Challenge to Statute of Limitations

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

***Respondent*.**

Mari C. Bush, Esq., Kay and Bush, LLC, Denver, CO, for petitioner.

Lynn E. Ricciardella, Esq., United States Department of Justice, Washington, D.C., for respondent.

OPINION AND ORDER

Block, *Judge*.

I. INTRODUCTION

The case before the court is a review of the Chief Special Master Golkiewicz's decision dismissing petitioner's claim for compensation under the National Vaccine Injury Compensation Program ("the Program"or "the Vaccine Act"),[1] 42 U.S.C. §§ 300aa-10 to -34. *Cloer v. Sec'y of the Dep't of Health & Human Servs.* ("*Cloer I*"), 2008 WL 2275574 (Sp. Mstr. Fed. Cl. May 15, 2008). The issue in this case surrounds the proper interpretation of the Vaccine Act's limitations period.

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[*] This opinion originally was issued under seal on November 25, 2008. The court afforded the parties an opportunity to propose redactions in the opinion prior to its publication, but no such redactions were proposed. Accordingly, the opinion is herein reissued for publication, unsealed.

[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq.* (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act").

Section 300aa-16(a)(2) of Title 42 bars all petitions seeking compensation for any vaccine injury from an on-Table vaccine "after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." The issue facing this court is whether the limitations period commences according to a subjective test of when a petitioner discovered the existence of the disease or malady, or according to the more restrictive objective test of when the earlier of the first particular symptom of a vaccine injury occurred or the onset of that injury manifested.

The petitioner, Dr. Melissa Cloer, had received a series of three Hepatitis B ("Hep-B") vaccinations starting in fall of 1996, after which, in 1997, she began to experience neurological symptoms indicating a demyelinating[2] disease. *Cloer I* at *1–*3. Following a May 1998 MRI revealing lesions on the white matter of her central nervous system, Dr. Cloer received differential diagnoses that included Multiple Sclerosis,[3] Singular Sclerosis, Lyme Disease, and acute disseminating encephalomyelitis, along with other demyelinating processes. *Id.* Over the next several years, Dr. Cloer suffered other episodic symptoms consistent with a demyelinating disease. *See id.* at *2–*4. On November 26, 2003, Dr. Cloer received a "provisional" diagnosis of MS by her treating neurologist, Dr. Wood. *Id.* at *2.

But it was not until September 16, 2005, that Dr. Cloer filed a petition pursuant to the Program, alleging that she "had sustained and/or significantly aggravated Multiple Sclerosis as a result of receiving Hep-B immunizations in 1996 and 1997." *Id.* at *1. After receiving evidence, holding a hearing, and receiving post-hearing briefs from both parties, Chief Special Master Golkiewicz dismissed Dr. Cloer's petition because she failed to file within three years of the first symptom or manifestation of onset of her claimed vaccine injury, which occurred in 1997. *Id.* at *8–*10. Accordingly, the Chief Special Master applied the more restrictive construction of the Vaccine Act's limitations period. *Id.* at *4–*9. The Chief Special Master rejected petitioner's contention that the more lenient subjective view of the limitations period should control. *Id.* at *8–*9. Petitioner had argued that because it was not until November, 2003, that Dr. Cloer received

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[2] "Myelin is a collection of lipid fats and proteins that sheaths the long extensions of nerve cells (neurons) called axons. Myelin considerably increases the speed that nerve signals (impulses) move down the axons." Multiple Sclerosis Encylopaedia, *Myelin*, http://www.mult-sclerosis.org/myelin.html. Thus, a demyelinating disease is one in which lesions appear in the myelin sheaths surrounding the axons.

[3] *See* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1669 (30th ed. 2003) (observing that the etiology—also known as "causation"—of MS is unknown). MS is:

> a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of lesions of the white matter are weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that *the term multiple also refers to remissions and relapses that occur over a period of many years*. Four types are recognized, based on the course of the disease: relapsing remitting, secondary progressive, primary progressive, and progressive relapsing.

even a provisional diagnosis of MS, not only would it be wholly unfair to apply the more restrictive objective limitations period, it would also violate Fifth Amendment constitutional precepts of equal protection and due process. *See id.* at *9 n.10.

On June 16, 2008, petitioner filed in this court a Motion for Review of the Chief Special Master's decision. Pet.'s Mem. 34. Thus, petitioner asks this court to reverse the Chief Special Master's May 15, 2008 decision dismissing her petition based on the restrictive view of the Program's three-year statute of limitations. Pet.'s Mem. 1. Upon review, for the reasons stated below, the court holds that the Chief Special Master applied the correct legal standard in determining that Dr. Cloer's petition was untimely. Furthermore, as also explained below, the court rejects petitioner's constitutional arguments.

II. BACKGROUND[4]

A. Dr. Cloer's Medical History

Dr. Cloer was born on January 22, 1968. Prior to exhibiting symptoms of a demyelinating disease, Dr. Cloer had no significant medical issues and enjoyed generally good health. She began the series of Hep-B vaccinations on September 3, 1996, and received the second vaccination on November 11, 1996. Thereafter, Dr. Cloer reported that after these two vaccinations, she experienced some numbness and tingling. Dr. Cloer received her third and final Hep-B vaccination on April 3, 1997.

About a month after her final vaccination, Dr. Cloer began to experience numbness in her left forearm and hand. Dr. Cloer also began to experience what she described as an "electric shock sensation," with "electric like sensations going down the center of her back to both feet with forward head flexion." This sensation is known as Lhermitte sign, a common symptom of MS.[5]

Concerned about these symptoms, Dr. Cloer went to her family physician, who prescribed Motrin. This initial set of symptoms mostly disappeared over the next few months. In 1998, about a year after receiving her final vaccination, Dr. Cloer sought treatment from Dr. Michael Andrew Meyer, an expert in the field of neurology with a specialty in MS. Dr. Meyer ordered an MRI, and

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[4] The facts, drawn from the pleadings and the Chief Special Master's decision in *Cloer I*, are undisputed, although, as the Chief Special Master characterized it, "the significance of the facts is the consequence of the dispute." *Cloer I* at 3.

[5] Also known as Lhermitte's sign or Lhermitte's phenomenon. Lhermitte sign is defined as:

> the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; *seen mainly in multiple sclerosis* but also in compression and other disorders of the cervical cord.

DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1700 (30th ed. 2003) (emphasis added).

based on the results indicating white matter lesion, concluded that Dr. Cloer could have MS, lyme disease, acute disseminating encephalomyelitis, or other demyelinating processes. Dr. Meyer noted "[p]robable early inactive non-progressive CNS [central nervous system] demyelination/MS," even though he had not yet *diagnosed* Dr. Cloer with MS. Dr. Meyer later recalled that during the period he treated Dr. Cloer, "[t]here had been no manifestation of onset of *clinically definite* multiple sclerosis." *Id.* at *3 (quoting Dr. Meyer's affidavit (emphasis added)). Dr. Meyer explained in his affidavit to the Chief Special Master that Dr. Cloer did not meet "*formal diagnostic criteria* for *clinically definite* MS" because Dr. Cloer's "singular demyelinating change could have remained a clinically isolated event with no sequela." *Id.* (quoting Dr. Meyer's affidavit (emphases added)).

On May 6, 1999, Dr. Cloer received a neurological examination from Dr. Ted Colapinto. Dr. Colapinto noted Dr. Cloer's medical history, described above, and recorded her complaints of numbness in her face, arms, and legs, and her difficulty in walking. Dr. Colapinto noted that Dr. Cloer's symptoms likely represented a demyelinating disease. During a follow-up visit on June 3, 1999, Dr. Colapinto observed improvement in Dr. Cloer's lower extremities, though she still had weakness and numbness in her right leg. At this time, Dr. Colapinto again expressed his concern that Dr. Cloer had a demyelinating disease.

Dr. Kevin Wood, who evaluated Dr. Cloer on November 26, 2003, recorded that Dr. Cloer believed that her symptoms began in 1997. Discussing the patient history, Dr. Wood noted that Dr. Cloer also had episodes of variable weakness and numbness of her legs, and an episode of numbness of her right face. Dr. Wood's notes also record that Dr. Cloer's 1998 MRI was reportedly suspicious for demyelinating areas, though her spinal cord MRIs were unremarkable. After examining Dr. Cloer's medical history and 1998 MRIs, Dr. Wood gave her a "provisional diagnosis" of MS. Dr. James P. Metcalf, who evaluated Dr. Cloer for Social Security Disability in 2004, observed that she began to show symptoms consistent with MS in 1997; though these symptoms waxed and waned until fall of 2003, when Dr. Cloer began to manifest "full blown" MS. *Id.* at *2.

B. *Cloer I*

Dr. Cloer filed her petition for compensation for a vaccine injury on September 16, 2005. Chief Special Master Golkiewicz received multiple pleadings and affidavits concerning whether Dr. Cloer's petition was timely under the Program. *Cloer I* at *1. Chief Special Master Golkiewicz also held a telephonic hearing to elicit testimony from Dr. Meyer, after which both parties filed additional post-hearing briefs. *Id.* In evaluating Dr. Cloer's petition for compensation for a vaccine injury under the Program, the Chief Special Master provided an extensive discussion of Dr. Cloer's medical history and the affidavits of her physicians.

Dr. Cloer's argument made to the Chief Special Master is as follows: although Dr. Cloer experienced Lhermitte sign, a symptom of MS, in 1997, and each doctor who saw Dr. Cloer for her demyelinating disease traced its first symptoms back to her Lhermitte sign in 1997, Dr. Cloer did not receive a *clinically definite diagnosis* of MS prior to 2003 and neither she nor her physicians were aware of a potential link between MS and vaccinations until after 2003. *Cloer I* at *1–*7. To be sure, Dr. Cloer argued that, based on the knowledge available at that time to the medical community, a diagnosis of MS due to a vaccine injury must be predicated on a manifestation of MS that lasted for at least six months. *Id.* at *9–*10. Thus, Dr. Cloer argues that she could not have petitioned for

compensation because no member of the medical community at large would have linked her demyelinating disease problems to the Hep-B vaccinations until after 2003, and as such, her petition was timely. In essence, Dr. Cloer was asking the Chief Special Master to apply the more lenient subjective statute of limitations period of *Sentes v. United States*, 57 Fed. Cl. 175, 181 (2003) (holding that limitations period begins to run only when subtle symptoms of injury become clearly apparent and the onset of the manifestation of the disease can be diagnosed by a "treating physician").

In rejecting Dr. Cloer's argument, the Chief Special Master relied on the Federal Circuit opinion in *Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353 (2007), in applying the restrictive view of the limitation's period of the Vaccine Act. The Chief Special Master observed that in *Markovich*, the Federal Circuit interpreted the Vaccine Act's limitations period to commence on the date the first symptom or manifestation of onset occurs, even though that indication may well be "before many practitioners would be able to recognize with reasonable certainty the nature of the injury." *Id.* at *5 (quoting *Markovich*). The Chief Special Master also noted that this view is supported by the Federal Circuit's recognition of the disjunctive test in § 16(a)(2) that emphasized the distinction between a symptom and a manifestation of onset.[6] *Id.*

In reviewing Dr. Cloer's medical history and the affidavits of her doctors, the Chief Special Master concluded, based on the affidavits of Dr. Cloer and her doctors, that the first manifestation of MS was the Lhermitte sign—the "electric shock sensation" that she experienced in 1997. *Id.* at *6–*8. Moreover, The Chief Special Master observed that even Dr. Meyer, Dr. Cloer's expert and the neurologist who treated Dr. Cloer in 1998, considered in retrospect that the first Lhermitte sign was her first symptom of MS. *Id.* at *9.

Accordingly, based on § 16(a)(2) of the Vaccine Act as informed by *Markovich*, the Chief Special Master interpreted the statute of limitations to trigger on the first symptom or manifestation of onset of MS in 1997, rather than adopt the more lenient view of the limitations period endorsed in *Setnes*—when the petitioner received her definitive diagnosis of the disease in 2003. *Id.* at *8–*10. The Chief Special Master ultimately concluded that Dr. Cloer's petition, filed in 2005, was well outside the statute of limitations, which ended in 2000. *Id.* at *7–*8. Thus, Chief Special

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[6] The court stressed that the words "symptom" and "manifestation of onset" are in the disjunctive as used in the Act and that the words have different meanings. Thus, symptom "may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury," whereas a manifestation of onset "is more self-evident of an injury and may include significant symptoms that clearly evidence an injury." Accordingly, the court found that the Act's statutory standard of first symptom or manifestation of onset could include subtle symptoms that a petitioner would recognize "only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury" and would be "recognizable to the medical profession at large but not necessarily to the parent."

Cloer I at *5 (quoting *Markovich*) (internal citations omitted).

Master Golkiewicz dismissed Dr. Cloer's petition as barred by the Vaccine Act's three-year statute of limitations.

Finally, as to the constitutional arguments, the Chief Special Master noted in passing that petitioner had raised certain constitutional objections, which respondent vigorously opposed. *See Cloer I* at *9 n.10. Nevertheless, the Chief Special Master rejected these contentions without much comment because they were "not well-developed" and because similar or the same provisions were "analyzed and found to pass constitutional scrutiny" in *Luez v. Secretary of HHS*, 63 Fed. Cl. 602 (2005). *Id.*

III. DISCUSSION

Section 12(e)(1) of the Vaccine Act establishes this court's jurisdiction to review decisions of a Special Master upon a properly filed motion for review. 42 U.S.C. § 300aa-12(e)(1); *see also* Vaccine Rule 23; *Phillips v. Sec'y of the Dep't of Health & Human Servs.*, 988 F.2d 111, 112 (Fed. Cir. 1993). This court may embark on one of three courses of action when reviewing a special master's decision in a vaccine case. *Rupert v. Sec'y of Dep't of Health & Human Servs.*, 55 Fed. Cl. 293, 297 (2003). This court may:

> (A) uphold the findings of fact and conclusions of law of the Special Master and sustain the Special Master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the Special Master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the Special Master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2)(A)–(C); *see also* Vaccine Rules 27, 36(b).

This court, moreover, should apply a different standard depending on what aspect of the Special Master's decision is under review.

> These standards vary in application as well as in degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by [the Federal Circuit], as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard.

Saunders v. Sec'y of Dep't of Health & Human Servs., 25 F.3d 1031, 1034 (Fed. Cir. 1994) (*quoting Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10); *see also Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274, 1277 (Fed. Cir. 2005) ("Under the Vaccine Act, the [United States] Court of Federal Claims reviews the special master's decision to determine if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (internal

quotations omitted)). The practical effect of this structure is to give the Special Master's determinations decisional effect, and to place this court in the role of a reviewing court. *Munn*, 970 F.2d at 869.

Clearly, the "not in accordance with law" standard is applicable in the case at bar because the primary dispute—interpretation and application of the appropriate limitations period—is a pure legal issue. *See Hines v. Sec'y Dep't of Health & Human Servs*., 940 F.2d 1518, 1527 (Fed. Cir.1991). And so are the constitutional claims attacking the Vaccine Act's limitation period. *See Leuz*, 63 Fed. Cl. at 607–12; *Blackmon v. American Home Prods.*, 328 F.Supp.2d 647, 655–57 (S.D. Tex. 2004). Moreover, the petitioner also asserts an ancillary claim predicated on the arbitrary and capricious standard.

The court's inquiry in this regard must focus on whether the Chief Special Master examined the "relevant data" and articulated a "'satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *See Hines*, 940 F.2d at 1527 (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (applying a similar standard of review for agency rulemaking under the Administrative Procedure Act)); *see also Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (The "arbitrary and capricious" determination involves a "consideration of the relevant factors and whether there has been a clear error of judgment."). The scope of review under this standard is highly deferential and precludes this court from substituting its own judgment for that of the Special Master. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (*citing Bowman Transp. Inc. v. Arkansas-Best Freight System*, 419 U.S. at 286 (1973)).

To be sure, this court must even "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Id.* (internal citations omitted); *Hines*, 940 F.2d at 1527 ("If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate."). Furthermore, the Act makes clear that this court "is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Hodges v. Sec'y of the Dep't of Health & Human Servs*., 9 F.3d 958, 961 (Fed. Cir. 1993). Indeed, "[t]his is a standard well understood to be the most deferential possible." *Munn*, 970 F.2d at 870. Thus, the petitioner has a difficult row to hoe.

A. Was *Cloer I* "in accordance with law?"

With these standards in mind, the court turns to the two legal issues proffered by petitioner, the proper construction of the 36-month limitations period found in 42 U.S.C. § 300aa-16(a)(2), and the constitutionality of that section. Preliminarily, it should be noted that the statute of limitations issue goes to the heart of the jurisdiction of this court. This is so because the limitations period in the Vaccine Act "'is a condition on the waiver of sovereign immunity by the United States,' and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.'" *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367, 1370 (Fed. Cir. 2001) (quoting *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed. Cir. 2000)). Consequently, absent such congressional consent, this court lacks jurisdiction to grant relief. *See, e.g.*, *United States v. Testan*, 424 U.S. 392, 399 (1976); *United States v. Sherwood*, 312 U.S.

584 (1941). It is also beyond doubt that waiver of sovereign immunity must be strictly construed. *See United States v. Mitchell*, 445 U.S. 535, 538 (1980); *Markovich*, 477 F.3d at 1360 (observing that the Vaccine Act's limitation period must be "strictly and narrowly construed because it is a condition on the waiver of sovereign immunity by the United States"). Thus, it is critical for this court to construe the relevant statute of limitations properly.

Accordingly, the issue presented to this court is whether the Chief Special Master correctly construed the limitations period of 42 U.S.C. § 300aa-16(a)(2). It is worth repeating that, by its terms, it bars all petitions seeking compensation for any vaccine injury from an on-Table vaccine "after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." The Hepatitis-B vaccine, the alleged culprit in this case, is indeed an "on-Table" vaccine. 42 U.S.C. § 300aa-14.[7] Section 300aa-16(a)(2) was therefore the proper limitations period to apply in this case. There are several cases that address this provision and clarify its construction, although one is contrary to the other two.

The first piece of the puzzle is *Brice*, where the Federal Circuit held that equitable tolling does not apply to the Vaccine Act's statute of limitations, 42 U.S.C. § 300aa-16(a)(2). 240 F.3d at 1372–74. In so holding, the Federal Circuit noted that this statute of limitations "begins to run upon the first symptom or manifestation of the onset of injury, *even if the petitioner reasonably would not have known at that time that the vaccine had caused an injury*." *Id*. at 1373 (emphasis added). The *Brice* court apparently rejected the view (enunciated, as explained above, by petitioner in this court) that the limitations period begins only when a sufferer has reason to believe the vaccine caused the injury. To be sure, in explaining why this restrictive construction of the limitations provision buttressed the belief that the doctrine of equitable tolling does not apply to § 300aa-16(a)(2), the court observed that it would be "quite odd for Congress to allow a limitations period to run in cases in which a petitioner has no reason to know that a vaccine recipient has suffered an injury, but to provide for equitable tolling when a petitioner is aware that a vaccine has caused an injury but has delayed in filing suit." *Id.* The issue of how strict is *Brice*'s restrictive view of the Vaccine Act's limitations period was addressed by the Court of Federal Claims in *Setnes v. United States*, 57 Fed. Cl. 175 (2003).

In reviewing a claim alleging that the vaccine recipient suffered the injury of an autism spectrum disorder, the Court of Federal Claims in *Setnes* took a broad view of the Vaccine Act's statute of limitations. (It is thus the odd-man out in this set of cases.) The Setneses had argued that the 36-month statute of limitations should date from July 16, 1999, when AJ's pediatrician, for the first time, found that AJ was not meeting "*medically appropriate* development guidelines." *Id.* at 179 (emphasis in original). Specifically, the Setneses maintained that because of its unique nature, "there can be no 'manifestation of onset' [for autism spectrum disorder] until such time as the medical and psychological professionals verify through reliable medical and psychological means that a constellation of behaviors presented in a specific child meet [its] criteria." *Id.* In response,

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[7] *See* HRSA - National Vaccine Injury Compensation Program, http://www.hrsa.gov/Vaccinecompensation/table.htm (listing "VIII. Hepatitis B antigen-containing vaccines" on the Table).

the government, taking the more restrictive view, asserted that the plain language of the statute of limitations triggers only on "the occurrence of the first symptom" of the vaccine injury. *See id.* at 180.

In rejecting the government's restrictive view of the limitations period, the court concluded, based on expert evidence, that "the beginning stage of autism cannot be reduced to a single, identifiable symptom. . . . [m]any of the initial symptoms are subtle and can easily be confused with typical childhood behavior." *Id.* The *Setnes* court determined that autism was a special case, "as distinguished from other medical conditions," because "there is no clear start to the injury." *Id.* Moreover, the court interpreted the "first symptom" and the "manifestation of onset" in the statute of limitations to have different meanings, rejecting the government's contention that the "onset" was determined by the first symptom. *See id.* Significantly, the court construed the limitations provision's term "manifestation of onset" to mean that the resulting disease must be "manifest," *i.e.*, evident at the time, to trigger the statute of limitations. *Id.* at 180 (citing BLACK'S LAW DICTIONARY 867 (5th ed. 1979)). Thus, to the court, for diseases that develop "insidiously over time" in which the initial symptoms are not readily connected to any injury or disorder, the limitations period begins to run only when the manifestation of onset of a particular recognizable injury becomes evident. *See id.* The *Setnes* court concluded that because the special master improperly relied upon retrospective observations as to symptoms rather than contemporaneous medical conclusions as to the manifestation of the specific disease, the special master's decision was reversed and remanded. *Id.* at 180–81.

However, the validity of *Setnes* was made doubtful by the Federal Circuit in *Markovich*. Relying on *Setnes*, the Markoviches urged the Federal Circuit to interpret the Vaccine Act's statute of limitations to embody the more lenient subjective standard commencing only when the petitioner knew that an injury or symptom had occurred. *Markovich*, 477 F.3d at 1356. In affirming the Court of Federal Claims, the Federal Circuit emphasized that the Vaccine Act's statute of limitations is disjunctive, and thus is triggered by *the earlier* of the first symptom of a vaccine injury or the manifestation of its onset. *See id.* at 1357–58. The court further distinguished between a "symptom" and "a manifestation of onset," giving semantic effect to the statute of limitations' syntactic distinction. *Id.* at 1358. The court explained that:

> [a] symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury. A manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury.

Id. Significantly, the *Markovich* court criticized the *Setnes* rationale as problematic because it "effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was appreciable evidence shoring a symptom *and* manifestation of the injury," in contrast to the clearly disjunctive language in the text. *Id.* (emphasis in original). The Federal Circuit also criticized *Setnes* for suggesting that a "subtle symptom or manifestation of the onset of the injury . . . that would be recognizable to the medical profession at large but not to the parent, would not be sufficient to trigger" the statute of limitations. *Id.* Instead, the Federal Circuit cited *Brice* for support, emphasizing that the Federal Circuit has consistently interpreted the Vaccine Act's statute of limitations to be triggered even on "subtle symptoms or manifestations of onset of the injury." *Id.*

Turning to the case at bar, what is fatal to petitioner's cause is that despite protests to the contrary, petitioner relies for support almost exclusively on *Setnes*. Thus, petitioner contends that her petition was timely within the statute of limitations because she only received a "clinically definite" diagnosis of MS in 2003, less than 36 months before filing her petition for compensation in 2005. Pet.'s Mem. 2, 15–21. Petitioner focuses on the medical criteria for *diagnosing* MS and the practical difficulties in doing so given the vagaries of the disease (which is a good application of the holding in *Setnes*), yet astonishingly claims that it is *Markovich* and § 300aa-16(a)(2) that requires that a doctor definitively connect the first symptom to a particular disease before the statute of limitations begins to run. *See, e.g.*, Pet.'s Mem. 3 (referring to "diagnosis or manifestation of onset *of Multiple Sclerosis*" (emphasis added)), 4 & n.2 (discussing criteria for diagnosing MS and how petitioner did not meet these diagnostic criteria), 8–9 (discussing Dr. Meyer's affidavit that he could not diagnose petitioner with clinically definite MS in 1998). According to petitioner, because she did not receive a definitive diagnosis of MS until 2003, and there was no reason for the medical community to suspect a vaccine link to MS until 2004, she could not have had a symptom or manifested the onset of MS as judged by the medical community at large. *Id.* at 11–14. In other words, petitioner is arguing for this court to apply the holding of *Setnes*, which is of questionable validity and not binding upon this court, rather than the valid binding precedent of *Markovich*.

Similarly, this court must reject petitioner's contention that the Chief Special Master's dismissal was legally erroneous because he relied on an idiosyncratic definition of a "vaccine injury." This argument dresses the *Setnes* wolf in sheep's attire. Once again, petitioner argues that a "vaccine injury," the *sine qua non* for recovery under the Vaccine Act, by definition, cannot be based on the first occurrence of a symptom but is instead contingent on a physician's ultimate diagnosis of a disease based on a particular set of symptoms. Pet.'s Mem. 15–16. In other words, because the first set of symptoms may be premature for a definitive diagnosis of a disease, it cannot itself constitute a "vaccine injury." According to the petitioner, the clock should begin to run only when it was known that the vaccine caused the complained-of specific injury. Nevertheless, all of this is contrary to *Markovich*, which held that the limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming. 477 F.3d at 1358–59. Logical or not, unfair or not, this is what Congress intended. *Id.* at 1358 ("the terms of the Vaccine Act demonstrate that Congress intended the limitations period to commence to run *prior* to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action" (emphasis added)); *Brice*, 240 F.3d at 1368–69, 1372–73. Indeed, the Chief Special Master, applying *Markovich*, correctly observed that "[t]he Federal Circuit was very clear that diagnosis is not the test for the purposes of the statute of limitations." *Cloer I* at *8.

Another of petitioner's objections is based on based on 42 U.S.C. § 300aa-11(c)(1)(D)(I). This provision requires that a petition under the Vaccine Act contain an affidavit or other supporting material that a petitioner has "suffered the residual effects or complications of such illness, disability, injury, or condition for more than six months after the administration of the vaccine." Characterizing this language as a tolling provision, petitioner argues that the Chief Special Master erred in dismissing her petition because the limitations period could not begin to run until her injury persisted for six months, which did not occur until 2003–04 (which would thus make her claim timely). Pet.'s Mem. 22–23. The assertion that this requirement has any relation to the Vaccine Act's 36-month statute of limitations has no support in case law, the text of the statute of limitations, or the text of this six-

month requirement. Section 300aa-11(c) merely contains the requirements for a petitioner to commence an action before the vaccine special master, one of which is a declaration that petitioner suffered from effects or complications six months after the administration of the vaccine. 42 U.S.C. § 300aa-11(c)(1)(D)(I). Therefore, this language is a condition precedent to the filing of the petition, not a limitations period cutting off the availability of an action.

Although also labeled as an arbitrary and capricious, abuse of discretion argument, petitioner's final "in accordance with law" question raises constitutional arguments. Pet.'s Mem. 30–33. These arguments, arising out of the Fifth Amendment's Due Process Clause, U.S. CONST. amend. V, are twofold: (1) that the Chief Special Master's construction of the Vaccine Act's limitations period impermissibly, in violation of equal protection precepts, discriminates against those victims of vaccines who, like Dr. Cloer, suffer from injuries that cannot be diagnosed within the Act's 36-month limitations period; and (2) that this construction denies petitioner her due process rights. Similar arguments have been addressed by various courts. And each of these courts have uniformly rejected those arguments.

For instance, in *Leuz* , the parents of a boy who died following a vaccination raised arguments similar to those made by Dr. Cloer in the case at bar, although a different limitations period provision of the Vaccine Act was involved. 63 Fed. Cl. at 604. At issue was 42 U.S.C. § 300aa-16(a)(3), which requires that claims alleging death due to a vaccination be filed within 24 months of the death. The *Leuz* petitioners contrasted this with the non-death injuries, for which § 16(a)(2) (the provision at controversy in our case) provides for a 36-month limitations period following the injury. *Id.* The petitioners did not dispute that they filed their petition 33 months after their son's death, but instead contended that the Act violated their rights to equal protection and due process because the limitations period for death injuries was shorter than the 36-month limitations period for all other injuries under the Vaccine Act. *Id.* at 605.

The court rejected their constitutional arguments. Opining that rational basis review applied because the petitioners' Vaccine Act equal protection discrimination claims[8] did not implicate any fundamental right, the court concluded that the differing limitations period passed constitutional muster so long as it was reasonably related to a permissible government goal. *See id.* (citing *Black v. Sec'y of Health & Human Servs*., 93 F.3d 781, 787 (1996)). The court noted that "Congress is not obligated to extend the coverage of the Vaccine Act cases to all person [sic] suffering a vaccine-related injury." *Id.* (citing *Black*, 93 F.3d at 788; *Califano v. Boles*, 433 U.S. 282, 296 (1979)). Contrary to petitioners' claim that it was irrational, the court found logical reasons, and thus a rational basis, for the distinction—while in a non-death case, symptoms continue to evolve, and may need more time to diagnose, the events surrounding a death are static, and preclude the injury from worsening, changing, abating, or evolving. *See id.* at 608–09.

[8] "Although," as the court explained, "the Fifth Amendment contains no equal protection clause," it forbids discrimination that is "'so unjustifiable as to be violative of due process.'" *Id*. at 608 (quoting *Schneider v Rusk*, 377 U.S. 163, 168 (1964) (quoting *Bolling v. Sharpe*, 347 U.S. 497, 499 (1954))).

Nor did the limitations period run afoul, according to the court, of either substantive or procedural due process. Thus, the court determined that the limitations period did not violate substantive due process because it neither shocked the conscience nor interfered with any right implicit in the concept of ordered liberty. *Id.* at 609–10 (citing *United States v. Salerno*, 481 U.S. 739, 746 (1987) (quoting *Rochin v. California*, 342 U.S. 165, 172 (1952))). Rather, the court noted that the 24-month period is "rationally related to the Act's dual purposes of settling claims quickly and easily, without collateral litigation, and protecting manufacturers from uncertain tort liability." *Id.* at 610. In sum, the court concluded that "the petitioners have not persuasively argued that the statute of limitations has operated in any manner contrary to its legislative purpose." *Id*. Similarly, the court concluded that the limitations period did not violate procedural due process. *Id.* at 610–11. Because petitioners had no vested right in any claim for damages until there is a final judgment, they had only a "unilateral expectation" that does not rise to a level of entitlement. *Id.* (citing *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972); *Hammond v. United States*, 786 F.2d 8, 12 (1st Cir. 1986)). Moreover, the court, in applying the balancing test under *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976),[9] concluded that tolling the limitations period as petitioners requested would come at a great societal cost by harming public health and thus would be inconsistent with the Act's overall statutory scheme. *See id.* at 611–12.

An even more apropos case is *Blackmon.* In facing equal protection and due process constitutional challenges to § 16(a)(2)'s 36-month limitations period—the same limitations period in controversy here—the court faced an argument similar to that made by Dr. Cloer: the Vaccine Act's limitations period unconstitutionally discriminated against those with latent, slow-developing vaccine injuries that cannot be fully diagnosed until the 36-month period has run. *Blackmon*, 328 F.Supp.2d at 655. While emphasizing that the limitations period did impose a hardship on some people, because the statute of limitations was only subject to rational basis review, the 36-month limitations period bore a clear and logical connection to a "repose" purpose of the Vaccine Act in protecting vaccine manufacturers from open-ended lawsuits in order to maintain the supply of vaccines. *Id.* (citing *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994)).

The plaintiffs' other Fifth Amendment argument (again, much like Dr. Cloer's) asserted that the Act's statute of limitations, expiring before the plaintiffs knew or could have known of their children's vaccine injuries, violated the constitutional guarantee of due process. *See id.* at 655–56. In rejecting petitioners' assertions, the court observed the well-settled rule that "[t]he Due Process Clause does not entitle every litigant to a hearing on the merits in every case," and emphasized that statutes of limitations are themselves common and unremarkable means to avoid stale claims and provide an end-date to potential litigation. *See id.* at 656. The court noted that plaintiffs failed their burden to prove that the Vaccine Act's limitations period was "wholly arbitrary." *Id.* (citing *Montagino v. Canale*, 792 F.2d 554, 557 (5th Cir. 1986)). Indeed, to the court, "[t]he mere fact that

[9] These factors include: "(1) the strength of the private interests that would be affected by the official action; (2) the 'risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards,' and (3) 'the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.'" *Leuz*, 63 Fed. Cl. at 611 (quoting *Mathews*, 424 U.S. at 335).

certain victims fail to discover and file their claims before the limitations period expires, while regrettable, does not render the limitation unreasonable." *Id.* at 656–57 (quoting *Ciccarelli v. Carey Canadian Mines Ltd.*, 757 F.2d 548, 555 (3d Cir. 1985) ("Because statutory periods are in some sense arbitrary, the period to initiate suit occasionally expires before a claimant has sustained any injury . . . or before the claimant knows he has sustained an injury. . . .")). Instead, the limitations period was constitutional because "it is reasonably calculated to serve a permissible legislative goal." *Id.*

The equal protection and due process arguments proffered by petitioner in the case at bar must be rejected for the reason the virtually-same arguments were rejected by the *Luez* and *Blackmon* courts—there can be no question that applying the Vaccine Act's limitation period is rationally related to the dual legitimate legislative purposes undergirding the Vaccine Act: (1) the settling of claims quickly and easily,[10] and (2) the protecting of manufacturers from uncertain liability making "production of vaccines economically unattractive, potentially discouraging vaccine manufacturers from remaining in the market." *Brice*, 240 F.3d at 1368. And because petitioner also lacks a vested property interest in her claim, it is difficult to see a Fifth Amendment due process violation.

B. Was *Cloer I* an Abuse of Discretion or Arbitrary and Capricious?

Turning to this set of objections, petitioner contends that it was an abuse of discretion or arbitrary and capricious of the Chief Special Master not to account for the "insidious[]" development of MS and the difficulties in diagnosing it, especially as MS was not listed as an injury for any vaccine on the Table. Pet.'s Mem 23–24. In other words, petitioner maintains that an exception should have been made to the restrictive view of the limitations period because petitioner did not and could not receive a definitive diagnosis for her particular demyelinating disease until 2003. *See, e.g.*, Pet.'s Mem. 21, 24. Yet this is another *Setnes* argument that petitioner tries to dress up in new garb. At its heart it is a matter of the interpretation of the limitations period provision, which is a pure legal issue, not one of whether the Chief Special Master's marshaling of the evidence was unreasonable or arbitrary.

Nevertheless, even using the arbitrary and capricious rubric, and contrary to petitioner's contention, the Chief Special Master did not abuse his discretion, nor act arbitrarily or capriciously, in refusing to carve out an atextual exception for petitioner's particular claimed injury. The record would not allow it. To be sure, as far back as 1998, plaintiff's own expert, Dr. Meyer, considered MS to be a possible cause of Dr. Cloer's symptoms. *Cloer I* at *1 ("May 15, 1998 record of UM-Columbia noted '[p]robable early inactive non-progressive CNS [central nervous system] demyelination/MS'"). In retrospect, Dr. Meyer similarly concluded that the first sign of MS was the Lhermitte Sign that Dr. Cloer experienced in 1997. *Id.* at *4. It is this Lhermitte sign, which was then indicative of MS and remains so today, that was the "first symptom" (or perhaps even a "manifestation of onset") of what is by definition a vaccine injury under the Act. *See Brice*, 240 F.3d at 1373 (observing that for the purpose of the Vaccine Act's limitations period the first symptom of

[10] *See* H. R. REP. NO. 99-908, at 17, *reprinted in* 1986 U.C.C.A.N. at 6358 ("[M]uch of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner.").

a vaccine injury may predate the final diagnosis of a disease). That Dr. Cloer was finally able, in 2003, to definitively attach a particular name to the symptoms that she had on and off for six years does not and cannot mean that she did not suffer a vaccine injury until 2003. The statute of limitations does not provide "first clinically *definitive* symptom or manifestation of onset of a medical syndrome;" rather, it is sparked by the "first symptom or manifestation of onset of a vaccine injury." *See* 42 U.S.C. § 300aa-16(a)(2).

Furthermore, there is other evidence in the record that supports the Chief Special Master's conclusion that the first symptoms of MS occurred prior to 2003. In May 1999, Dr. Colapinto traced the beginning of petitioner's neurological symptoms, which "likely represent demyelinating disease," back to the numbness in Dr. Cloer's left arm and hand that accompanied her Lhermitte sign. *Id.* at *1. Similarly, Dr. Wood, in 2003, and Dr. Metcalf, in 2004, both trace petitioner's first symptoms back to her neurological problems of 1997. *See id.* at *2.

Similarly, petitioner's other "arbitrary and capricious" arguments are really "not in accordance with law" objections. Nor are they persuasive. For instance, the petitioner asserts that by rejecting the application of *Setnes* to the instant facts, *Cloer I* is not only not in accordance with law, but also is an abuse of discretion or arbitrary and capricious. Pet.'s Mem. 24–25. The Chief Special Master concluded, and this court agrees, that *Setnes* does not apply to the instant facts, *Cloer I* at *4–*5, and that even if it did, as stated above, *Setnes* is contrary to *Markovich*, which, unlike *Setnes*, is binding upon this court. Petitioner likewise contends that the Chief Special Master's decision to deny compensation is arbitrary and capricious because it violates the remedial purpose of the Vaccine Act, which is demonstrated by its generous provisions and because it is less adversarial than a product liability lawsuit. Pet.'s Mem. 25–28. But of course, it is the duty of the Chief Special Master here to enforce the Vaccine Act's specific limitations provision, the meaning of which is the best exemplar of congressional intent. *See Nixon v. United States*, 506 U.S. 224, 232 (1993) (observing "the well-established rule that the plain language of the enacted text is the best indicator of intent").

Yet another "arbitrary and capricious" objection by petitioner is that the Chief Special Master ignored her proffered "unrebutted expert testimony" supporting her position. Pet.'s Mem. 29–30. This objection is also vague and not well-developed. Petitioner failed to detail which "unrebutted" testimony the Chief Special Master ignored. In fact, there is no evidence that Chief Special Master Golkiewicz ignored or failed to weigh testimony on *any medical issue* in the case. Yet there remains one other proffered argument that falls into the "vague and not well-developed" category. In asserting yet another *Setnes* argument, petitioner argues that because she did not find out until 2005 that the Hep-B vaccinations to which she traces her MS contained Thimerosal, the court must liberally construe the Vaccine Act's 36-month statute of limitations to begin to run on the diagnosis of the disease rather than trigger on its first symptom or the manifestation of its onset.[11] Pet.'s Mem. 33–34. Petitioner further claims that *Cloer I* fails to address recent concerns on Thimerosal and the potential

[11] Thimerosal is a compound that had been added to vaccines as a preservative and is the subject of a number of claims alleging that it causes vaccine injuries, most notably but not exclusively autism spectrum disorder. *See generally* Thimerosal in Vaccines, http://www.fda.gov/CBER/vaccine/thimerosal.htm. An examination of the effects of Thimerosal is beyond the scope of this opinion.

bearing of this new information on the accrual of her claims under the Vaccine Program. Pet.'s Mem. 34. Besides the fact that there is no evidence that petitioner raised this issue before the Chief Special Master, neither the potential effects of Thimerosal nor its inclusion in the Hep-B vaccine have any bearing on whether petitioner sought compensation within three years of the first symptom or manifestation of the onset of her demyelinating disease.

To be sure, this court has an enormous amount of sympathy for petitioner's predicament—MS is not easy to diagnose, its etiology remains largely unknown, and its manifestation and symptoms are episodic, waxing and waning, disappearing and recurring. *See* note 3, *supra*. That petitioner may be without relief for her MS gives this court no small measure of discomfort. But, as the Federal Circuit noted in *Brice*, weighing the pros and cons of a particular statutory scheme is a problem for Congress to address. 240 F.3d at 1373. The 36-month limitations period of the Vaccine Act is neither unlawful nor unconstitutional. Nor was the Chief Special Master's decision arbitrary, capricious, or an abuse of discretion.

IV. CONCLUSION

For the foregoing reasons, the court **AFFIRMS** the Special Master's decision. The court, accordingly, dismisses the petition with prejudice.

IT IS SO ORDERED.

s/ Lawrence J. Block
Lawrence J. Block
Judge